

## SUMMARY OF PRODUCT CHARACTERISTICS

### 1 NAME OF THE MEDICINAL PRODUCT

SimAlvia 60 mg/300 mg, soft capsules

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each soft capsule contains 60 mg alverine citrate and 300 mg simeticone.

Excipient with known effect: soya lecithin (traces).

For a full list of excipients, see section 6.1.

### 3 PHARMACEUTICAL FORM

Capsule, soft.

Soft oblong capsule, size 6, shiny opaque white, containing a thick whitish suspension.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Relief of abdominal pain in irritable bowel syndrome.

SimAlvia, soft capsule is indicated in adults only.

### 4.2 Posology and method of administration

#### Posology

#### *Paediatric population*

The safety and efficacy of SimAlvia, soft capsules in children under 18 years of age have not been established.

#### Method of administration

For oral administration

#### *Adults (including the elderly)*

1 soft capsule two to three times daily at the beginning of meals.

### 4.3 Contraindications

Paralytic ileus

Intestinal obstruction

Use in pregnancy and lactation

History of allergic reaction or intolerance to alverine or to any of the excipients  
Hypersensitivity to peanut or soya.

#### **4.4 Special warnings and precautions for use**

Other causes of gastro intestinal pathology should be ruled out, and patients not improving after 2 weeks of treatment should be reviewed by physician.

#### **4.5 Interaction with other medicinal products and other forms of interaction**

None known.

#### **4.6 Fertility, pregnancy and lactation**

##### Pregnancy

Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity (see section 5.3).

A moderate amount of data on pregnant women indicate no malformative or fetoneonatal toxicity of alverine citrate. There are no data from the use of simeticone or the combination in pregnant women.

As a precautionary measure, it is preferable to avoid the use of SimAlvia, soft capsules during pregnancy.

##### Breastfeeding

It is unknown whether alverine citrate or simeticone and their metabolites are excreted in human milk. This medicinal product should be avoided during breastfeeding.

##### Fertility

There are no data on the effects of alverine citrate or simeticone on human fertility.

#### **4.7 Effects on ability to drive and use machines**

SimAlvia, soft capsules have no influence on the ability to drive and use machines.

#### **4.8 Undesirable effects**

The side effects listed below have been reported at frequencies corresponding to: very common ( $\geq 1/10$ ), common ( $\geq 1/100$  to  $<1/10$ ), uncommon ( $\geq 1/1,000$  to  $<1/100$ ), rare ( $\geq 1/10,000$  to  $<1/1,000$ ), very rare ( $<1/10,000$ ). Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.

Due to the presence of alverine:

##### **Hepatobiliary disorders**

*Very rare*

Liver disorders which resolve after treatment discontinuation.

### **Respiratory, thoracic and mediastinal disorders**

*Very rare*

Laryngeal oedema

### **Skin and subcutaneous tissue disorders:**

*Very rare*

Urticaria

### **Vascular disorders**

*Very rare*

Shock

### **Reporting of suspected adverse reactions**

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the MHRA Yellow Card Scheme

Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard).

## **4.9 Overdose**

No case of overdose has been reported.

# **5 PHARMACOLOGICAL PROPERTIES**

## **5.1 Pharmacodynamic properties**

Pharmacotherapeutic group: Musculotropic antispasmodic / Anti-flatulent, ATC code: A03AX58

Alverine citrate is a non-atropinic, papaverine-like musculotropic antispasmodic.

Simeticone is an inert substance which has a physical action by altering the surface tension of gas bubbles, leading to their coalescence.

## **5.2 Pharmacokinetic properties**

Simeticone is not absorbed from the gastrointestinal tract. Following oral administration, it is eliminated in unchanged form in the faeces.

A clinical study confirmed that alverine crosses the gastro-intestinal barrier with inter-individual variability. However in most patients, plasma concentrations were lower than 1ng/ml.

Steady-state for plasma concentrations of alverine were reached within 5 days, therefore no more increase in plasma levels is expected in case of repeated administration for a period of time longer than 7 days.

### **5.3 Preclinical safety data**

Non clinical studies of single and repeated dose toxicity, genotoxicity, toxicity to reproduction and development provide evidence that alverine citrate has no significant systemic toxicity potential.

Simeticone is not absorbed from the intestinal lumen. Systemic effects are therefore not expected.

No long term studies to evaluate carcinogenicity have been performed in animals with alverine citrate or with the combination of alverine citrate and simeticone. Simeticone was shown to have no carcinogenicity potential.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

#### Soft capsule shell:

Gelatin

Glycerol

Titanium dioxide (E171).

#### External lubricant composition:

Soya lecithin

Fractionated coconut oil.

### **6.2 Incompatibilities**

Not applicable.

### **6.3 Shelf life**

30 months

### **6.4 Special precautions for storage**

Store below 25°C.

Keep in outer carton in order to protect from light.

**6.5 Nature and contents of container**

PVC/Aluminium thermoformed blister of 10 soft capsules.

Pack sizes of 10, 20, 30, 40, 60 or 90 capsules.

Not all pack sizes may be marketed.

**6.6 Special precautions for disposal**

No special requirements.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

**7 MARKETING AUTHORISATION HOLDER**

Laboratoires GALENIQUES VERNIN

20, rue Louis-Charles Vernin

77190 Dammarie-les-Lys

FRANCE

**8 MARKETING AUTHORISATION NUMBER(S)**

PL 15490/0001

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

08/12/2014

**10 DATE OF REVISION OF THE TEXT**

27/07/2016